Greater New York Hospital Association
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Kenneth E. Raske, President

March
Fourteen
2007

Andrew C. Von Eschenbach, M.D.
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: 2006N-0062: Proposed Rule Regarding Expanded Access to Investigational Drugs for Treatment Use

Dear Dr. Von Eschenbach:

I am writing on behalf of the Greater New York Hospital Association to share with you concerns that have been raised by some of our members with respect to the Food and Drug Administration's proposed rule regarding *Expanded Access to Investigational Drugs for Treatment Use.* By way of background, GNYHA represents over 250 not-for-profit and public hospitals and continuing care facilities that are concentrated in the New York City region but located through New York, New Jersey, Connecticut, and Rhode Island.

Our members are committed, caring advocates for their patients and therefore firmly support greater access to potentially life-saving treatments. As a result, they appreciate the goals and efforts undertaken by the FDA to accomplish this. However, at the same time, they are concerned that aspects of the proposed rule may negatively affect the ability of the health care community to undertake meaningful and definitive clinical trials. In short, they are concerned that aspects of the proposed rule may undermine the current process for evaluating whether drugs are effective and safe. I will outline some of the specific concerns that members have raised.

Difficulty in Application of Certain Requirements: First, a concern has been raised that it may be difficult to apply the requirement that a patient may have access to an investigational drug if the patient's physician concludes that the probable risk to the patient is greater than the probable risk from the disease or condition. Investigational drugs, by definition, are not fully understood in terms of risks and benefits. Therefore, it would be difficult for a patient's physician to make the assessment required, perhaps to the detriment of the patient.

Potential Impact on the Viability of Clinical Trials: Second, questions have been raised about the impact of the proposed rule on the viability and integrity of clinical trials moving forward. We recognize that the proposed rule requires the FDA to determine that providing an

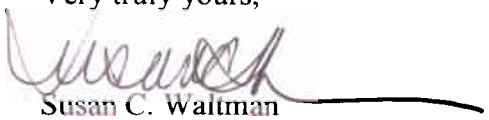
investigational drug will not interfere with the initiation, conduct, or completion of clinical investigations before the FDA grants patients expanded access to the investigational drug. However, there is concern that allowing access to investigational drugs outside of clinical trials will result in a "decreased number of patients enrolled in trials, less stringent clinical trial protocols, and a reduced amount of useful data produced by trials." We have been informed that this may occur because patients will be more likely to choose to receive drugs through the expanded access process rather than through a study that might involve a control agent. We recognize that the proposed rule provides that a patient would not be able to receive the drug through the expanded access process if they could participate in a clinical trial. However, we understand that this criterion may be difficult to apply and administer.

Impact on Sponsorships/Payment: Third, in light of the foregoing factors, some of our members are concerned that pharmaceutical companies may become less willing to sponsor clinical trials. In addition, payers and health plans may also be less willing to reimburse for even routine care of patients receiving investigational drugs off protocol.

Emergency Use Exception: Finally, one member pointed out that, as the proposed rule addresses the process for obtaining drugs for emergency use, it imposes some of the obligations of a sponsor on the physician/institution seeking to administer the drug to the patient. While the member recognizes that the FDA needs to obtain certain data, there was concern that the significant obligations imposed on providers under such circumstances might impede their ability/willingness to seek the drugs for their patients. In addition, the member was concerned that the emergency use exception might be defined too narrowly and thus reduce access to drugs for this purpose.

Thank you for the opportunity to submit comments on behalf of our members. If you have any questions regarding the foregoing, please let me know.

Very truly yours,



Susan C. Waltman
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